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(54) Product integrity verification apparatus

(57) A method and apparatus for verifying the composition of a moving product employs a source of near infra-red radiation for illuminating the product. Means for receiving data relating to the location of the product and using said data to receive radiation from the source reflected from the located product and a spectrometer for receiving the radiation from the radiation receiving means and providing an output corresponding to the intensity of the received radiation at a number of different wavelengths are provided. Also provided is means for determining whether or not the product is within predetermined integrity criteria on the basis of the spectrometer output.

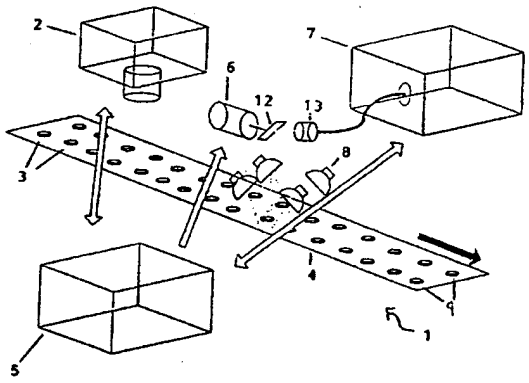

Fig 1

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Description

This invention relates to systems for verifying the integrity of products such as chemical tablets. Because of the very nature of chemical tablets, particularly those of the medical type, a high degree of quality control is required in their manufacture. It is not acceptable to have even a small percentage of such a product fall outside strict quality requirements, as this could have serious consequences for an end-user of the product.

To ensure the quality of the product being filled on a production line it is a requirement that every tablet/capsule is verified. In known filling lines this verification is carried out using a vision system to check that the size, shape and colour of each tablet are within preset limits. Only tablets that pass these quality checks are used to fill bottles.

However, such systems still have a number of problems, for example, on clinical packaging lines tablets and capsules of different types and concentrations (including placebos) are often intentionally or coincidentally visually identical. Therefore, such visual verification of the tablets/capsules is not sufficient to distinguish different product types and levels of active component.

The present invention is directed toward overcoming this and other problems.

According to the present invention there is provided an apparatus for verifying the composition of a moving product, the apparatus comprising:

a source of near infra-red radiation for illuminating the product;
means for receiving data relating to the location of the product and using said data to receive radiation from the source reflected from the located product;
a spectrometer for receiving the radiation from the radiation receiving means and providing an output corresponding to the intensity of the received radiation at a number of different wavelengths; and
means for determining whether or not the product is within predetermined integrity criteria on the basis of the spectrometer output.

The product may be a chemical product, for example, a tablet or capsule.

The radiation receiving means may employ a galvo-mirror, the position of which is altered dependent upon received location data in order to target a located product.

The spectrometer may comprise means for splitting received radiation in to a number of wavelengths for detection by a photo-diode array.

The illuminating source may comprise one or more lamps. The apparatus may be arranged to verify the quality of one or more streams of product at the same time, using only one spectrometer.

In a preferred embodiment, two lamps are provided for each stream of product to be tested, each lamp being directed at the stream at an angle of approximately 45°. Each stream is usually a single line of product.

The system may be controlled by a control PC via a dedicated interface card.

The product location data may be provided by a known vision system located upstream from the apparatus.

The apparatus may further comprise a calibration target mechanism for providing a calibration target for the radiation receiving means. The calibration target mechanism may be arranged to move a calibration target into the field of view of the radiation receiving means and/or may be arranged to provide a calibration target during operation of the apparatus.

Means may be provided for calibrating the apparatus both on start-up and during operation. The calibration means may employ compensation representing a dark output from the spectrometer and an output from a reference target.

The determining means may employ a Gaussian weighted function in order to reduce the effects of noise.

The determining means may employ a weighting factor in its determination function. The weighting factor may be employed to emphasise features that do not change between samples of the same tablet type.

The apparatus may be arranged so that a product of unknown characterstic can be fed through it and the characteristics of the product determined and used in future verification. If the apparatus is arranged in this way, it may also be arranged such that it provides an indication to the user of any additional special checking step that may be required if the new product is of similar composition to previously tested products.

A corresponding method is also provided.

The invention is capable of real time verification of 100% of the product.

The invention employs Near Infra-Red (NIR) to verify the composition of tablets and capsules before they are filled into bottles. This invention can therefore be used, for example, in combination with known fillers on known packaging lines.

The Near Infra-red Spectroscopy employed is based on the principle that certain molecules absorb radiation in the near infra-red wavelength region. The amount of absorption is dependent on the molecule type and its concentration. This phenomenon may be used to distinguish tablets/capsules even when they appear visually identical.

One example of the present invention will now be described with reference to the accompanying drawings, in

which:

Figure 1 is a schematic block diagram of an apparatus according to the present invention;
Figure 2 is a diagram showing an illuminating means for use in the apparatus of the present invention;
Figure 3 is a schematic diagram of a radiation obtaining means for use in the present invention;
Figure 4 is a diagram showing a calibration mechanism, for calibrating an apparatus of the invention;
Figure 5 is a schematic block diagram showing control circuitry that may be employed with the present invention;
Figure 6 is a timing diagram showing the control sequence of the apparatus of the invention; and
Figure 7 is a schematic diagram showing a spectrometer that may be employed with the invention.

Referring to Figure 1, an apparatus 1 according to the invention is shown. This apparatus is employed in combination with a known vision system 2 which detects the location of product 3 passing along a moving conveyor 4.

In use tablets/capsules 3 are fed from a hopper (not shown) onto the conveyor 4 in two lines 9 by vibratory feeder stages. They pass beneath the vision system 2 where they are checked for size, shape and colour. Positional data is also acquired so that the apparatus 1 can be directed to acquire spectra from the tablets/capsules. Product position data is provided from the vision system 2 to control circuitry 5, which may comprise a combination of a PC and customised electronics, as described below. The control circuitry 5 controls radiation receiving means 6 and a spectrometer 7. It may also, optionally, control illuminating means 8.

The position information and the known speed of the conveyor 4 allow the control circuitry 5 to calculate the position the radiation receiving means 6 must be moved to in order to collect radiation from each product as it passes a detection point.

The radiation receiving means 6 collects radiation from each tablet/capsule of product and focuses it onto the optical fibre input of a spectrometer 7. The spectrometer 7 splits the radiation into a number of wavelengths which are detected by a photodiode array (not shown). The current from each photodiode is integrated for a preset period and then converted into a digital signal by an A/D converter. This data is transmitted over a high speed serial link back to the control circuit 5. The spectrum is then processed by the control circuit 5 and compared with the 'model' spectra for the type and dosage level of the tablet or capsule expected. If the similarity is within preset limits then the tablet will be accepted, otherwise it will be rejected.

There are several constraints on the apparatus 1 of the invention due to the filler design and through-put requirements with which it may be operated. These are that: fill rate can be up to 750 tablets per minute per channel; conveyor belt speed can be in the region of 200mm/s; two streams per channel may be provided; stream centre lines can be in the region of 28mm apart; tablets may be up to +/-6mm from a centre line; tablets in the two streams may be coincident; smallest tablets/capsules are approximately 5mm in diameter, and tablets may touch, giving a minimum tablet separation of 25ms worst case; tablets/capsules can vary in size from approx. 5mm diameter, 3mm thick to 20mm diameter, 6mm thick; tablets may be in any orientation; if tablets are embossed or engraved on one side only, either the marked or clear side may be uppermost. A channel is usually considered to comprise a conveyor, inspection system and verification system.

Furthermore, there should be little or no adjustment required to the apparatus 1 when changing over from one tablet type to another. The apparatus 1 should be self-calibrating and not require a spectrometry 'expert' to set up the system for a new tablet type.

The apparatus 1 should be sensitive to distinguish between a very high percentage of different tablet types and between a high percentage of tablet concentration levels. As actual sensitivities will vary from tablet to tablet, and cannot be predicted for tablets not actually analysed, the sensitivity limits must be determined empirically and can only be defined for particular tablets and concentration levels.

Data processing should be algorithmic in order to aid validation of the process for Federal Drug Administration (FDA) approval of the apparatus 1.

The apparatus 1 has a number of environmental factors with which it should be able to cope. For example, operating temperature should preferably be in the range 10 to 30°C ambient. A cooling system (not shown) may be provided so that the local temperature ambient within the optics and electronics enclosures does not exceed 10°C above ambient (max. 40°C).

The radiation receiving means 6 should be decoupled from any sources of vibration on any filler used in combination with the apparatus, and bright external radiation should preferably be excluded from the scanning area.

The apparatus 1 should ideally not require (manual) re-calibration within the specified operating limits or after cleaning operations.

OPTICAL SET-UP

The radiation receiving means 6, shown in detail in Figur 3 is designed so that the intensity of reflected near infra-

red radiation is sufficient to allow the short detector integration times required typically 4ms, and arranged so that incident and reflected radiation is as far as possible independent of product tablet 3 position and orientation on the conveyor belt 4. As the conveyor belt 4 on which the tablets 3 lie may be contaminated with tablet dust and tablets 3 may be close together, radiation must be collected only from one tablet surface at any one time. To enable this a beam steering mechanism 12 is positioned using the tablet positional data obtained from the upstream vision system 2 so as to collect radiation from the tablet surface 3 only.

A window 11 protects the optical assembly from contamination and allows easy cleaning of the system.

An example configuration, shown in Figure 2, consists of 4 tungsten halogen lamps with metal reflectors to direct a high level of radiation in the NIR region towards the sampling position. Two lamps 8 are directed at each product line 9 from an angle of 45°. This method gives a variability in illumination intensity of approx. 10% over the variation in tablet position across the belt of each stream. This variability is measured on start-up of the apparatus and calibrated in software in control circuitry 5.

Radiation from a 2mm diameter spot, collected as near as possible normal to the tablet surface has been found to be an ideal area of radiation collection for this application. This ensures that radiation is collected only from the tablet (even for the smallest tablets) 3 and reduces the tablet and capsule surface curvature effects that would be more problematic for a larger collection area. The 2mm diameter spot is still large enough however to lessen the variances in spectra reflected from the surface due to embossing on the tablet. Specular reflection is reduced by mounting the radiation sources 8 at 45° to the tablet surface.

The collected radiation is focused by a lens 14 onto a 400μm fibre optic cable 13 which then couples the radiation into the spectrometer 7. Care is taken to ensure the numerical apertures are matched throughout the system. The spectrometer 7 employs a holographic grating 33 to split received radiation and direct it to a photo-diode array 30 (Figure 7).

An $AlSiO_2$ coated galvo-mirror 12 with a 10mm usable diameter aperture is used to direct radiation from tablets 3 at various positions across the conveyor belt 4.

To achieve the required sensitivity the 2mm spot must be positioned on the centre of the tablet with an accuracy of better than, in this example, 0.7mm in the X and Y directions.

The consistency of spectra from tablets 3 at different points across the belt 4, from different spectrometers 7 and over extended times periods with varying environmental conditions is of utmost importance.

CALIBRATION

To achieve this either acquisition conditions must be identical and stay constant, or any variations must be calibrated out. The apparatus is designed to minimise the variations between product streams and spectrometers 7 but small (yet significant) variations will still be present which may also vary with time. To ensure the best quality spectra each channel will perform an initial set-up calibration at power on then periodically re-calibrate itself as the machine is running.

The calibrations are required for positional accuracy, variability in spectrometer characteristics, and variations in reflected radiation levels.

Initial set-up is done manually and is only required on assembly of each channel or if a component is moved or replaced. Calibration is required for each stream.

Positional set-up is performed by placing a set-up calibration target (not shown) on the conveyor 4 underneath the vision system 2 and apparatus. The set-up calibration target should be parallel to the direction of tablet movement. Calibration marks on the set-up target represent tablet positions for the two streams about each centre line. The calibration marks are located by the vision system. The NIR system is adjusted so that radiation is collected from the correct position downstream of each of the calibration marks. This creates a calibration file relating vision system calibration mark position to galvo-mirror angle.

The set-up calibration target has a height of, in this example, approx. 4.5mm above the belt surface. This is the median of tablet heights. Variations in tablet scan position due to changes in tablet height are small enough so that recalibration is not required for each different tablet. Any variations that do occur are consistent for a particular tablet type and height.

On power-up or channel reset the apparatus 1 checks that the radiation from a run calibration target 20 is within preset tolerances over the range of tablet positions across the belt. This ensures that all lamps 8 are functional and that the radiation reading means 6 is not contaminated. A run calibration target 20 with a standard reflectivity may be used to ensure measurements are calibrated to the same standard even across different lines or spectrometers 7. The radiation reading means 6 and spectrometer 7, together with any control circuitry should are encased in this example to NEMA12 standard (approximate to IP62) to prevent dust contamination.

The run calibration target mechanism 19 is shown in Figure 4. In a 'run' mode the reference target 20 is rotated through 90° by motor 17 to allow tablets to pass either side of a central bar 18. As well as supporting the reference target 20 the bar 18 also acts as a physical separator between the two product lines. When a power up/system reset cal-

ibration is carried out the target 20 is rotated back across the belt 4 (once the belt has been cleared of tablets/capsules) allowing the galvo-mirror 12 to scan the length of the target. Position sensors 21 confirm that the target 20 has fully rotated. In the 'run' position the central portion of the calibration target 20 is still within the field of view of the galvo-mirror 12. This allows periodic re-calibration of the spectrometer 7 'on the fly' without rotating the reference target 20 and clearing the conveyor 4.

A 'flat field' calibration is carried out to compensate for variances in illumination/reflection intensity (at each of the sampled wavelengths) over the range of possible tablet/capsule sample positions.

The galvo-mirror 12 acquires spectra over the 'field of view' for each line at regular steps. The dark current is also measured before each scan. The intensity at each wavelength and each position is normalised giving a set of gain and offset correction values. The gain and offset corrections are applied to the raw spectra acquired in subsequent tablet/capsule scans. Linear interpolation is used to determine the corrections for positions between the sample points.

Periodic calibration compensates for variances in the spectrometer response over time. Whenever there is a gap of greater than 14ms between target acquisition times the apparatus 1 calibrates itself.

There are two stages to this re-calibration:

1. The galvo-mirror 12 moves to its 'dark scan' position where no radiation is collected by direction towards a target 31 (Figure 3). A spectrum is acquired to give the dark current for each spectrometer photodiode 30 (Figure 7).
2. The galvo-mirror 12 moves to collect radiation from the reference target 20. A spectrum is acquired and the gain and offset pairs adjusted so that the spectrometer response is normalised.

For periodic calibration the gain and offset pairs for each wavelength are globally adjusted for each of the scan positions across the conveyor 4.

A NIR control/interface card 15 is mounted in one of the PCI interface slots in a control PC 16 to provide control circuitry 5. All data processing is carried out by the PC 16, only the lowest level control and interface functions are performed by the NIR card 15.

All programmable devices are arranged to allow programming in situ.

The galvo-mirror 12 is required to drive a 10mm usable aperture $AlSiO_2$ mirror to direct the reflected beam. From the optics geometry in this example the mirror is required to scan over a 40mm line corresponding to a 23 optical (11.5 mechanical) swing in under 3ms. A 10 bit D/A converter 31 output to the servo controller gives a positioning accuracy of approx. +/-0.1mm, which is better than the positioning accuracy required. The position feedback signal from a servo controller to the NIR control card 15 confirms the position of the mirror.

To direct the galvo-mirror 12 to the 'dark scan' target an additional 40° of movement is required, giving an total excursion of approx. 63° optical (31.5° mechanical).

Whenever the conveyor 4 is stopped (due to a filler Emergency stop for instance) the power to the radiation source is removed to avoid possible heat damage to either the conveyor belt 4 or tablets/capsules 3 from prolonged exposure.

The calibration target 20 is moved using as small DC motor 17 with a friction drive to a target wheel 23. Through beam optical sensors confirm position.

The apparatus 1 verifies product integrity in a manner now to be described. Generally, only one type of product is present on each channel of the filler at any one time, therefore it is not necessary to identify each tablet/capsule of product only to verify that it is of the expected type and concentration on that channel at that time.

DATA ANALYSIS

The sequence of analysis operations is detailed below:

For calibration correction, raw spectrum data from the spectrometer 7 giving the reflected radiation intensities at intervals (eg. 3.8nm) are calibration corrected to give a 'standard' value independent of the spectrometer 7 and radiation receiving means 6 characteristics, using the algorithm:

$$Ical_n = \frac{Iraw_n - Idark_n}{Iref_{n,pos}}$$

where

n =	wavelength number (0 to 255 corresponding to 1.2 to 2.2μm)
$Ical_n$ =	calibrated intensity
$Iraw_n$ =	raw intensity value
$Idark_n$ =	intensity due to diode dark current
$Iref_{n,pos}$ =	intensity of reference target, interpolated from values obtained over range of tablet positions during calibration

The calibrated intensities are then smoothed using a Gaussian weighted function to reduce the effects of noise, using:

$$Ismoothed_n = \frac{100xIcal_n + 120x(Ical_n{-}1 + Ical_{n+1}) + 40x(Ical_{n-2} + Ical_{n+2}) + 20x(Ical_{n-3} + Ical_{n+3})}{280}$$

The data is then auto-scaled (mean centred over the range of wavelengths and scaled so that the variance of the scaled data is equal to 1, with a data range of +/-1) using:

$$Iscaled_n = \frac{Ismoothed_n - \overline{Ismoothed}}{[\sum_n (Ismoothed_n - \overline{Ismoothed})^2]^{1/2}}$$

This reduces the effects of different intensity values due to tablet orientation etc.

The 1st derivative of the data is taken to highlight differences in the slope and position of spectral features between different samples, using:

$$Ideriv_n = \frac{\delta Iscaled_n}{\delta n}$$

If the filler is in 'learn' mode (see below) the spectra for a number of tablets/capsules are acquired. The master model is created for that tablet/capsule type from the mean spectrum of the data, using:
where

$$Model_n = \frac{\sum_s Ideriv_{s,n}}{S}$$

$_s$ = Range variable for all spectra acquired
S = Number of spectra

As some spectral features vary between samples of the same tablet/capsule type (due to varying water content among other factors), a weighting factor is derived that gives more emphasis to features that do not change between samples of the same tablet/capsule type. This increases the resolving power of the apparatus 1 to distinguish between tablets that are very similar.

The weighting factor is derived from the standard deviation of the distance between the intensity values and the master model intensity at each wavelength, using:

$$DistModel_{s,n} = Ideriv_{s,n} - Model_n$$

$$SDModel_n = \sqrt{\frac{\sum_s (DistModel_{s,n} - \overline{DistModel})^2}{S}}$$

$$WF_n = SDModel_N^{\ 3}$$

The Euclidean distance of each sample within the model data from the model is calculated, with the weighting factor applied. The mean of this value is then used to determine the standard deviation for the model i.e. determine the distribution of distance measurements in the model sample set about the mean model spectrum. A normal distribution is assumed, using:

$$EuclidDistModel_s = \sqrt{\sum_n \frac{(DistModel_n)^2}{WF_n}}$$

$$SDModel=\sqrt{\frac{\sum_{s}(EuclidDistModel_{s}-\overline{EuclidDistModel})^{2}}{S}}$$

The number of samples required may be varied to enable an acceptable model standard deviation to be obtained.

The mean Euclidean distance for the model is expressed as a difference value in terms of the model standard deviation, by:

$$ModelDifferenceMean=\frac{\overline{EuclidDistModel}}{SDModel}$$

In 'run' mode the derived spectrum for each tablet/capsule sampled is compared against a master model spectrum.

The Euclidean distance between the derived intensity at each wavelength and the corresponding intensity for the model is calculated, with the weighting factor at each wavelength applied, with:

$$SampleDist=\sqrt{\sum_{n}\frac{(Ideriv_{n}-Model_{n})^{2}}{WF_{n}}}$$

The 'difference' value is calculated in a difference calculation from the distance values scaled in terms of the Model standard deviation by:

$$SampleDifference=\frac{SampleDist}{SDModel}$$

A limit is set that is a number of standard deviations from the Model difference value.

$$Accept\ Limit = Model\ Difference\ Mean + LimitSD \times ModelSD,$$

where *LimitSD* is the number of standard deviations away from the model difference mean that a sample difference value will be accepted as being the same as the same tablet/capsule type as the model. (A value for LimitSD of 3 gives a 99.7% probability based on the model data set).

Sample Difference > *Accept Limit* Reject tablet/capsule on NIR criteria

Sample Difference ≤ *Accept Limit* Accept tablet/capsule on NIR criteria

When the apparatus is implemented as part of a filler system the size, shape and colour checks are used in addition to the apparatus analysis to determine the validity of each tablet/capsule on the lines 9.

SOFTWARE

The diagram of Figure 6 gives the timing requirements for the worst case situation where two tablets are coincident at the sampling position. The PC/NIR control systems must acquire data and transfer data to a PC buffer memory 35 at this rate (i.e. within 7ms for a complete cycle). Processing of spectra can be done at a lower rate, within 12.5ms, assuming a maximum 'burst' rate for a channel of 80 tablets per second.

Transfer of spectrum data (256 x 16 bit words) to PC memory is carried out using Direct Memory Access (DMA) to avoid an unacceptable processor burden.

The software requirement for the apparatus 1 is split into two parts. The low level control of the Spectrometer 7 and NIR card 15 can be implemented using a Windows NT kernel device driver, for example, to achieve the low level control and timing requirements. The higher level sequencing and data processing is implemented using a user level Windows NT thread, for example.

Various functions are provided by a device driver for the set-up and operation of the NIR card 15.

Each tablet/capsule 3 identified by the vision system 2 is added to a list of targets for the apparatus 1. Each target has associated with it:

TargetID	This identifies the target
TargetPosition	The angular position of the galvo-mirror 12 to collect the reflected radiation from that tablet, which is

derived from the pixel position of the centre of gravity of the tablet determined by th vision system.

NIRSampleTime The time in ms that the NIR acquisition sequence should start. This is derived from the time that vision system acquired the image of the target centre of gravity plus the time taken for the tablet to move along the conveyor from the vision system to the NIR acquisition point. If the centre of gravity of two targets are less than 7ms apart the NIRSampleTime is adjusted so that one target is sampled slightly early and the other slightly late. In the worst case this gives a mis-position of 0.7mm.

PCBufferAddress The address of the buffer in PC memory where the NIR spectrum should be placed.

The parameter AcquisitionType determines the sample type to be made, with 0 - Normal scan, 1 - Dark scan. In dark scan mode the spectrum is acquired with the spectrometer shutter 32 closed. Note that this mode is only used during initial set-up and testing. Periodic calibrations with the associated filler operating direct the galvo-mirror 12 to the dark-scan target and acquire dark current values for the diodes with the shutter open.

In an interrupt routine, called periodically, the current time is compared with the sample time of the next tablet on the list. If they are the same, the NIR_Acquire function is called which passes the tablet ID, TargetPosition and PC Buffer Adddress to the NIR card 15. The NIR card 15 moves the galvo mirror 12 to the required position and a short period (eg. 3ms) later triggers the spectrometer 7 to start acquiring the spectrum. After the integration time the spectrometer 7 sends its data over a high speed serial link to a buffer memory on the NIR card 15. The data is then transferred using DMA access to the PC 16. The NIR card 15 raises an interrupt on completion of this transfer.

An Interrupt Handler routine is called on completion of the transfer an NIR spectrum to PC memory. It resets the interrupt request on the NIR card 15 and informs the NIR user level thread on the PC that data is available to be processed.

A user level Windows NT thread provides the interface to the rest of the system, coordinates the higher level control of the apparatus 1 and implements the processing of the raw data to determine whether a particular tablet should be accepted, rejected or re-cycled. It also provides the functions for on-line calibration and 'learn/verify' mode operation.

The external functions provided include: performance of processing on the specified spectrum data as detailed above. This function returns a value to indicate whether the target was accepted or rejected. If the apparatus 1 was unable to scan or analyse the target for any reason the function returns a 'don't know' value. The reason is also communicated to the channel control functions so that appropriate action may be taken.

Other functions include creating a new NIR master model, adding the most recently acquired spectrum to the model data set, allowing model acceptance limits etc. to be altered, getting an existing NIR model from the database, storing a new or modified master model in the database, causing an re-calibration sequence. The parameter 'type' selects either power on/system reset or periodic re-calibration.

A Calibrate Request function requests the channel controller to halt the passage of tablets/capsules 3 onto the conveyor belt 4, so that a 'gap' is created so that an on-line calibration sequence may take place. This function is only called if the targets on the belt are so tightly spaced that there have been no breaks between scans long enough to perform a calibration scan within a preset period.

Several functions are required for development and testing but are not used during the normal operation and calibration of the filler. The functions include: display of spectrum for specified sample (reference scan, dark scan or tablet/capsule scan) in 'real time'; processing stages may be individually enabled and disabled and/or stepped through;display of spectrum for specified model in 'real time'; dumping of spectrum data (at various stages of processing) for later off-line analysis; and logging of data/messages to a log file for debugging purposes.

OPERATION

The apparatus of the invention has various operating functions, which are set out below.

A master model for each tablet/capsule type is stored on a database. This model includes attributes of the tablet such as name, dosage, size, shape, colour as well as the NIR model.

The NIR master model defines the NIR spectrum characteristics of a particular tablet/capsule 3.

When a different tablet/capsule 3 is loaded onto the filler machine the operator is required to select the master model for that tablet/capsule from a selection menu.

If the tablet/capsule is of a new type not run on the filler before, the operator selects 'new tablet/capsule' and enters information on name, dosage etc.

The filler then transitions to either a 'verify mode' where the tablet loaded is compared with the master model in the case of a known tablet/capsule, or 'learn mode' where a new master model is created in the case of a new tablet/capsule.

When a tablet/capsule type is changed and a master model does not exist, a number of tablets/capsules are run through the system to create a new master model. The 'mean' spectrum of these tablets is used to create the model. This new model is compared against all previous master models stored on the apparatus to check that the new tab-

let/capsule type can be reliably distinguished from all existing master models. In the small minority of cases where tablets/capsules cannot be distinguished (see below), special operating procedures may independently confirm the identity of the tablet loaded into the filler.

After creation of the model the filler runs through the master model confirmation stage before allowing the operator to fill bottles in a 'run mode'.

The number of tablets required to create/confirm the model is dependent on the variability in the spectra acquired, but is typically a few hundred tablets. These tablets are re-cycled to the hopper.

The apparatus can be employed to verify product on plural groups of channels of a filler. Each channel of the filler is calibrated to the same standard, so the master model is independent of the line 9 used to acquire the spectra.

When a tablet/capsule type is changed and a master model already exists, a number of tablets/capsules are run through the apparatus. The 'mean' spectrum of these tablets/capsules is compared with the master model and if the difference values are within acceptable limits the tablet/capsule is accepted and the filler may be used to fill bottles in 'run mode'. If the difference is outside the limits the operator is informed that the wrong type of tablet may have been loaded.

The number of tablets required for confirmation is dependent on the variability in the spectra acquired, but is typically a few hundred tablets. These tablets are re-cycled to the hopper.

Once the identity of the tablets/capsules loaded into the filler has been confirmed, the operator may select a 'run mode'. The sequence of operations is automatic and requires no further operator interaction (apart from responding to alarms, refilling a hopper and emptying the reject bin).

Each tablet/capsule that has passed the size, shape and colour quality checks performed by the vision system is sampled by the spectrometer 7 and its spectrum compared with the master model. If the difference value between the sample and the master model is within preset confidence limits it is accepted and directed to the appropriate bottle to be filled.

If the spectrum of the tablet/capsule is outside the limits (or the size, shape and colour verification failed) the tablet/capsule is directed to a reject bin and a message logged.

Any large variations in reflected radiation intensity will be flagged to the operator as a possible fault on the system. This includes failure of one or more lamps 5, failure of the spectrometer 7, or dirt build up on the optical window 11.

Set-up of the radiation receiving means 6 is only required on initial commissioning or after a component replacement. This is a manual operation carried out by a technician using test equipment and restricted access maintenance screens. A monitor screen, keyboard and mouse are connected local to the channel control PC 16 for these operations.

The apparatus 1 should reliably accept the tablets/capsules of the expected type and dosage concentrations and reject all others, other than in the exceptional cases detailed below:

Exception A: It is accepted that in a small minority of cases where NIR signatures are weak and dosage levels are low, the apparatus may not be able to reliably distinguish between tablets/capsules of low concentration levels of the same active component. These exceptions will be recorded.

Exception B: In some cases tablets/capsules of different dosage levels of the same active component type may have the same concentration level per unit volume. The apparatus will not distinguish between these tablets/capsules, but as different dosages must be of a different size, the visual inspection system can distinguish between them.

Exception B should never occur as in the filler implementation the NIR verification is only required where the (rogue) tablets are of the same size, shape and colour as the expected type.

When a new master model is created for a new tablet/capsule type the newly created model is compared with all the previously created master models for other tablets/capsules. The 'difference' between the new model and the existing model is calculated for each case. Whenever the new model is inside the acceptance limit for an existing model (as is likely for exception A above) or the existing model is within the acceptance limits of the new model these similarities are recorded and highlighted to the operator. Thus a log is kept of small minority of cases where tablet/capsule types cannot be reliably distinguished. In these cases special operating procedures may be put in place to ensure that the tablets/capsules loaded onto the filler are verified using alternative off-line techniques.

The performance of the apparatus 1 is checked both during a power-up/system reset and automatically as the system is running. These checks/re-calibrations compensate for gradual variations in spectrometer performance and system failures. Virtually all mechanical, electrical or optical failures are detected either during the calibration process or cause a fail to safety where the acquired spectrum is outside the acceptance limits and tablets/capsules are directed to the reject bin. It is therefore extremely unlikely that a failure could give rise to a false accept of tablets.

Claims

1. An apparatus for verifying the composition of a moving product, the apparatus comprising:

   a source of near infra-red radiation for illuminating the product;
   means for receiving data relating to the location of the product and using said data to receive radiation from the source reflected from the located product;
   a spectrometer for receiving the radiation from the radiation receiving means and providing an output corresponding to the intensity of the received radiation at a number of different wavelengths; and
   means for determining whether or not the product is within predetermined integrity criteria on the basis of the spectrometer output.

2. An apparatus according to claim 1, wherein the product is a chemical product.

3. An apparatus according to any of the preceding claims, wherein the radiation receiving means employs a galvo-mirror, the position of which is altered dependent upon received location data in order to target a located product.

4. An apparatus according to any of the preceding claims, wherein the spectrometer comprises means for splitting received radiation in to a number of wavelengths for detection by a photo-diode array.

5. An apparatus according to any of the preceding claims, wherein the illuminating source comprises two lamps for each line of product to be tested, each lamp being directed at the line at an angle of approximately 45°.

6. An apparatus according to any of the preceding claims, wherein the apparatus is arranged to verify the quality of plural lines of product at the same time.

7. An apparatus according to any of the preceding claims, wherein the system is controlled by a control PC via a dedicated interface card.

8. An apparatus according to any of the preceding claims, wherein the product location data is provided by a vision system located upstream from the apparatus.

9. An apparatus according to any of the preceding claims, wherein the apparatus further comprises a calibration target mechanism for providing a calibration target for the radiation receiving means.

10. An apparatus according to claim 9, wherein the calibration target mechanism is arranged to move a calibration target into the field of view of the radiation receiving means and/or is arranged to provide a calibration target during operation of the apparatus.

11. An apparatus according to any of the preceding claims, wherein the determining means employs a Gaussian weighted function.

12. An apparatus according to any of the preceding claims, wherein calibration means are provided for calibrating the apparatus both on start-up and during operation.

13. An apparatus according to claim 12, wherein the calibration means employs compensation representing a dark output from the spectrometer and an output from a reference target.

14. An apparatus according to any of the preceding claims, wherein the determining means employs a weighting factor in its determination function.

15. An apparatus according to claim 14, wherein the weighting factor is employed to emphasise features that do not change between samples of the same tablet type.

16. An apparatus according to any of the preceding claims, arranged so that a product of unknown characterstic can be fed through it and the characteristics of the product determined and used in future verification.

17. An apparatus according to claim 16, arranged such that it provides an indication to the user of any additional spe-

cial checking step that may be required if the unknown product is of similar composition to previously tested products.

18. A method for verifying the composition of a moving product, the method comprising the steps of:

illuminating the product with a source of near infra-red radiation;
receiving data relating to the location of the product and using said data to receive radiation from the source reflected from the located product;
receiving the radiation and providing an output corresponding to the intensity of the received radiation at a number of different wavelengths; and
determining whether or not the product is within predetermined integrity criteria on the basis of the output.

19. A method according to claim 18, wherein the product is a chemical product.

20. A method according to claims 18 or 19, employing a galvo-mirror, the position of which is altered dependent upon received location data in order to target a located product.

21. A method according to claims 18, 19 or 20, wherein the method verifies the quality of two lines of product at the same time.

22. A method according to any of claims 18 to 21, wherein the product location data is provided by a vision system.

23. A method according to any of claims 18 to 22, wherein the determining step employs a Gaussian weighted function.

24. A method according to any of claims 18 to 23 further comprising a calibration step for calibrating the apparatus both on start-up and during operation.

25. A method according to claim 24, wherein the calibration employs compensation representing a dark output and an output from a reference target.

26. A method according to any of claims 18 to 25, wherein the determining step employs a weighting factor in its determination.

27. A method according to claim 26, wherein the weighting factor is employed to emphasise features that do not change between samples of the same tablet type.

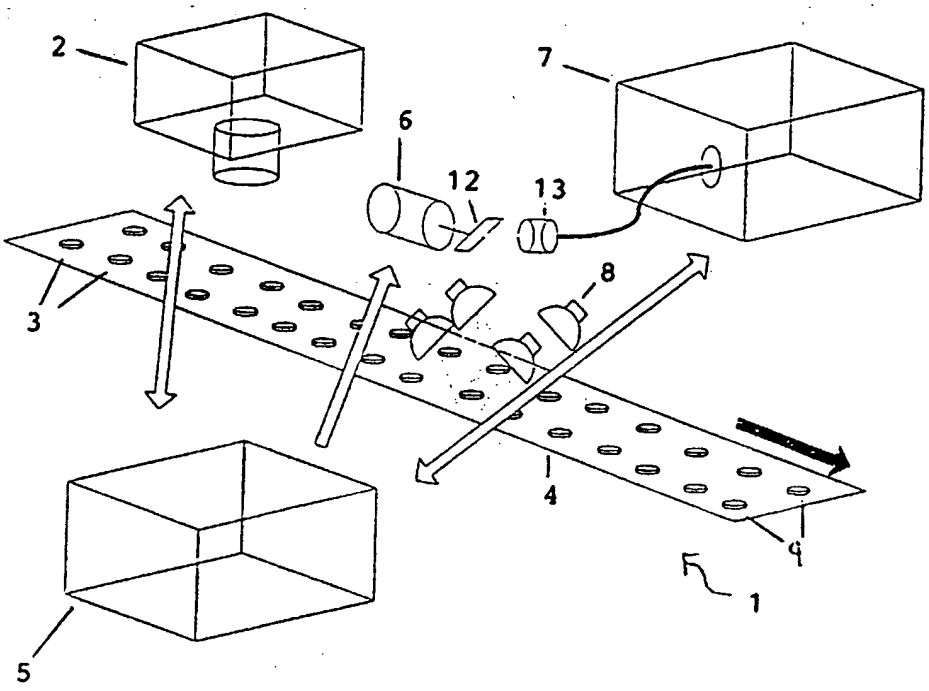

Fig 1

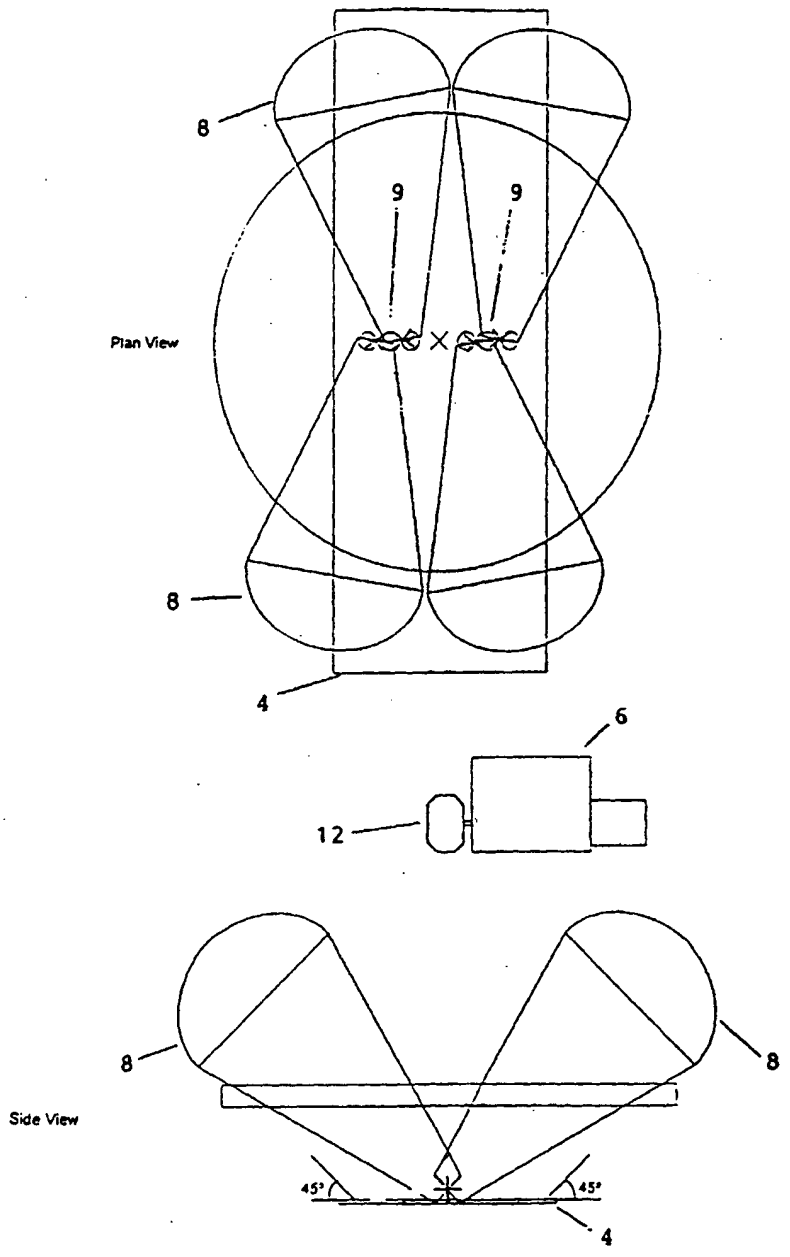

Fig 2

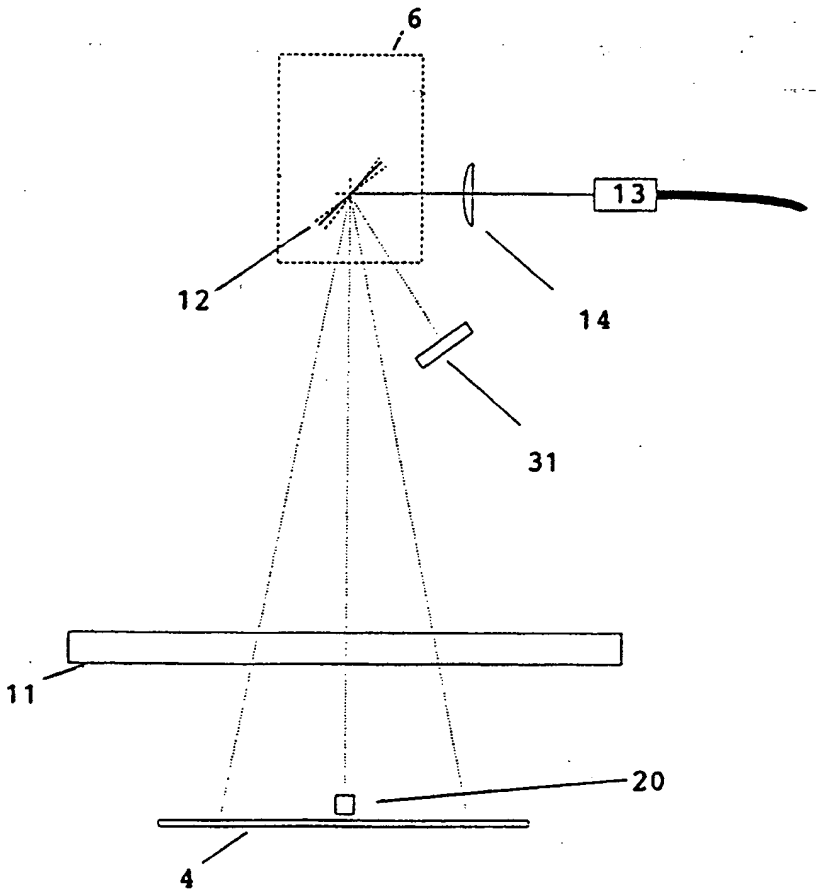

Fig 3

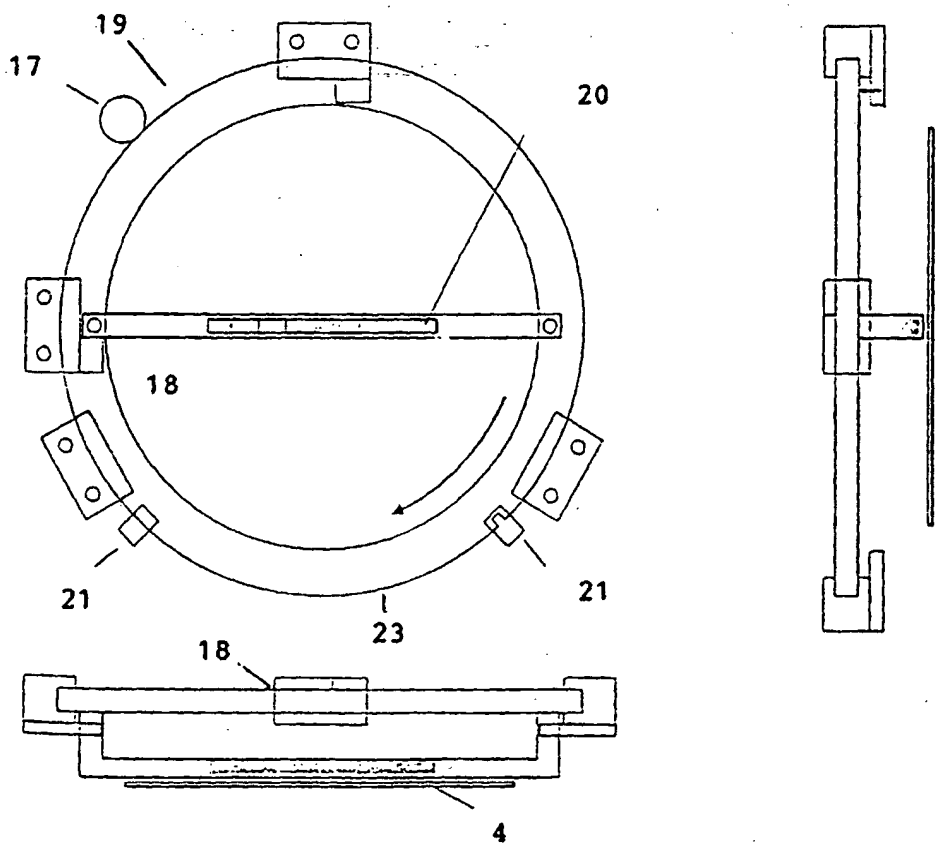

Fig 4

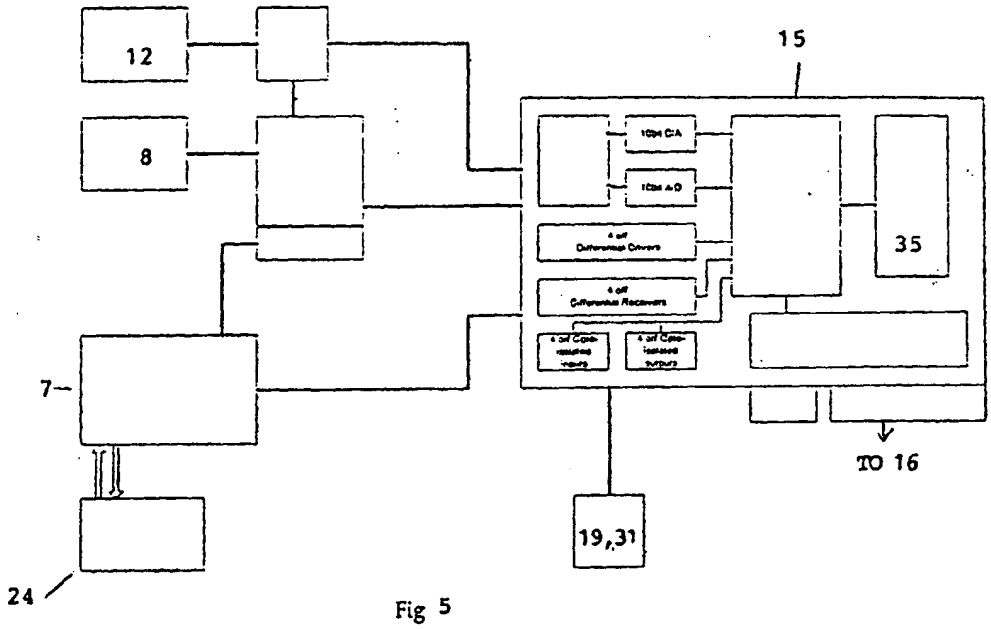

Fig 5

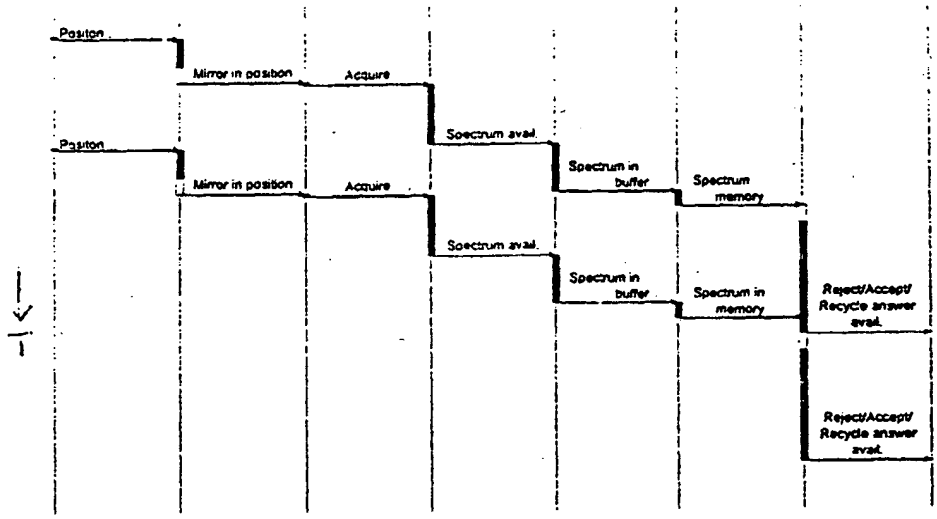
Position
Mirror in position
Acquire
Spectrum avail.
Spectrum in buffer
Spectrum memory
Position
Mirror in position
Acquire
Spectrum avail.
Spectrum in buffer
Spectrum in memory
Reject/Accept/ Recycle answer avail.
Reject/Accept/ Recycle answer avail.

Fig 6

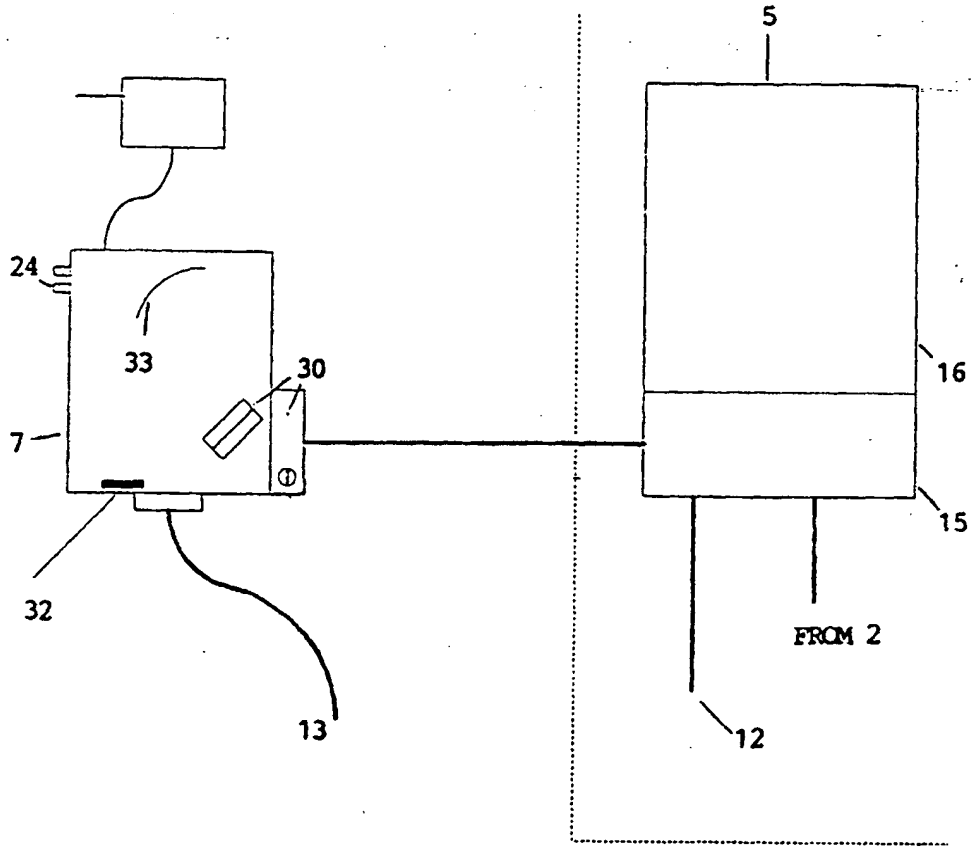

Fig 7.

European Patent Office

EUROPEAN SEARCH REPORT

Application Number
EP 97 30 4413

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.6)
Y	DE 43 40 795 A (LUCHT HARTMUT DR RER NAT) * column 2; figures 1-3 *	1,2,4-7, 18,19,21	G01N21/88 G01N21/35
Y	US 4 143 770 A (GRIMMELL WILLIAM C ET AL) * column 3, line 41 - column 4, line 56 *	1,2,4-7, 18,19,21	
A	SYKE G AND BURNS C: "CLOSED-CIRCUIT TELEVISION FOR THE INSPECTION OF FAST-MOVING SURFACES" JOURNAL OF THE INSTITUTION OF ELECTRICAL ENGINEERS, vol. 9, July 1963, pages 296-299, XP002047402 * figure 2 *	3,20	
A	PATENT ABSTRACTS OF JAPAN vol. 097, no. 008, 29 August 1997 & JP 09 089768 A (MITSUBISHI HEAVY IND LTD), 4 April 1997, * abstract *	1	
A	DE 44 41 686 A (BUEHLER AG) * column 2, line 45 - column 3, line 66 *	1	
A	US 5 440 127 A (SQUYRES HENRY P) * column 4, line 22 - line 33 *	8	

TECHNICAL FIELDS SEARCHED (Int.Cl.6)
G01N

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
THE HAGUE	18 November 1997	Tabellion, M

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
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